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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/848,752	05/18/2004	Joanne Paquin	PC 32131A	4652
29668	7590	07/14/2005	EXAMINER	
PFIZER, INC. 201 TABOR ROAD MORRIS PLAINS, NJ 07950			HENLEY III, RAYMOND J	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/848,752

Applicant(s)

PAQUIN ET AL.

Examiner

Raymond J. Henley III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 10/021,735.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/16/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**CLAIMS 20-23 ARE PRESENTED FOR EXAMINATION**

Applicants' Preliminary Amendment filed May 18, 2004 and Information Disclosure Statement filed July 16, 2004 have been received and entered into the application. Accordingly, the specification after the title has been amended; claims 1-19 have been canceled; claim 21 has been amended; and claims 22 and 23 have been added.

As reflected by the attached, completed copy of form PTO-1449, the Examiner has considered the cited references.

It is noted that while signed, Applicants' Preliminary Amendment is not dated (see the signature page). The Office has accepted the Preliminary Amendment on May 18, 2004 and this will be considered the official date.

***Specification***

The specification is objected to be the status of Applicants' parent application Serial No. 10/021,735 is incomplete. In Applicants' amendment to the specification after the title, ---, now U.S. Patent No. 6,858,646--- should be inserted after "filed May 5, 2000,".

***Drawings***

The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention (see the specification at pages 4 and 5). Applicants are required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

### ***Claim Interpretation***

In present claim 20-22 the term "homologous" has been employed in the expression "homologous suspension". This term is interpreted to mean "similar" by its plain meaning, (see Webster's II New Riverside University Dictionary, page 589, col. 1, last entry). Thus the expression is taken to mean a suspension similar to other suspensions which have a dispersion of solid particles in a liquid (see Webster's cited above at page 1167, col. 1, third entry, definition "5").

### ***Legal Standard for Anticipation/Inherency Under - 35 USC § 102***

To anticipate a claim under 35 U.S.C. § 102, a single prior art reference must place the invention in the public's possession by disclosing each and every element of the claimed invention in a manner sufficient to enable one skilled in the art to practice the invention. *Scripps Clinic & Research Foundation v. Genetech, Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1001 (Fed. Cir. 1991); *In re Donahue*, 766 F.2d 531, 533, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). To anticipate, the prior art must either expressly or inherently disclose every limitation of the claimed invention. *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber*, 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)); *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). To inherently anticipate, the prior art must necessarily function in accordance with, or include, the claimed limitations. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art recognize the inherent characteristics or the function of the prior art. *Id.* Specifically, discovery of the mechanism underlying a known process does not make it patentable.

***Claim Rejection - 35 USC § 102***

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20, 22 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Daley et al. (U.S. Patent No. 6,733,746, filed Jan. 31, 1997, cited by the Examiner).

Daley et al. teach a serum-free supplement composition which may support the growth of hematopoietic cells in culture (see the abstract). The composition may comprise a pyruvate compound (col. 18, line 41), at least one antioxidant compound, such as N-acetyl-L-cysteine and D,L-tocopherol acetate or derivatives (col. 11, lines 33, 38 and 40 and col. 18, lines 44 and 48), and at least one lipid, such as HUMAN EX-CYTE<sup>®</sup> (see col. 12, lines 10, 14 and 15 and col. 18, line 42). At col. 17, line 64, it is shown that the composition further comprises NaCl, i.e., salt/saline. At col. 18, line 52, an aqueous form of the composition is taught "both aqueous and dry forms" which places the aqueous form in the possession of the public. It is further taught that the composition may be sterilized by filtration (col. 18, lines 54-55), which, again, would place such concept in the possession of the public. Also, a buffer is taught that may be present, such as HEPES, (see col. 14, lines 22 and 28).

It is further taught that "If the ingredients of the supplement are prepared as separate concentrated solutions, an appropriate (sufficient) amount of each concentrate is combined [i.e., mixing or admixing, see col. 12, lines 57-58] with a diluent to produce a less concentrated formulation or a 1x formulation. Typically, the diluent for the subgroups used is water but other solutions including aqueous buffers, aqueous saline solution, or other aqueous solutions may be

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used according to the invention.” (see col. 17, lines 8-15; compare to present claim 20 “mixing together the components...”<sup>2</sup>) Insofar as the same components are being mixed together, it is believed a suspension, i.e, a “homologous suspension” would be produced because the composition would have water-insoluble particles dispersed in a liquid.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

*I* Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daley et al., as above, in view of Remington's Pharmaceutical Sciences (“Remington's”).

The difference between the above and the claimed subject matter lies in that Daley et al. fail to teach a step of centrifuging the resultant composition which would have been a “homologous suspension”.

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However, to one of ordinary skill in the art, the claimed subject matter would have been obvious because Daley et al. teaches filtering the resultant composition while Remington's shows that centrifugation is an alternative means for filtering (see page 1380, col. 2, second paragraph under "Centrifugation"). The skilled artisan would have been motivated to employ a centrifugal means of filtration because Daley et al. teach filtration in general (col. 18, line 55) thus indicating that all filtration methods should be useful.

*II* Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (U.S. Patent No. 5,633,285) in view of Remington's.

Martin teaches a composition comprising a wound healing composition comprising pyruvate; an antioxidant; and a mixture of saturated and unsaturated fatty acids (see the abstract). At col. 22, lines 22-25, the patentee teaches that "the combination of ingredients set out in the above embodiments..." which indicates that such ingredients are combined or mixed. Aqueous vehicles for the composition are taught for soaking gauze dressings (col. 27, lines 28-29) which may comprise ingredients such as buffers, preservatives, and tonicity adjusters such as sodium chloride, i.e., saline, (see col. 27, lines 32-38). Water is further taught as a solvent (col. 23, line 9) as well as in the expression "aqueous vehicles" (col. 27, line 28). The reference further teaches that the admixture may be "sterile filtered" (col. 23, line 13).

The difference between the above and the claimed subject matter lies in that Martin et al. fail to teach a step of centrifuging the resultant composition which would have been a "homologous suspension".

However, to one of ordinary skill in the art, the claimed subject matter would have been obvious because Martin et al. teaches filtering the admixture and also that "the ultimate

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therapeutic wound healing compositions are readily prepared using methods generally known in the pharmaceutical arts, (see col. 23, lines 17-19). Remington's shows that centrifugation is an alternative means for filtering (see page 1380, col. 2, second paragraph under "Centrifugation"). The skilled artisan would have been motivated to employ a centrifugal means of filtration because Martin teach filtration in general (col. 23, line 13) thus indicating that all filtration methods should be useful. Because the composition of the prior art would be an aqueous composition having the same components as the present claims, i.e., a buffered saline solution, pyruvate, an antioxidant and fatty acids, i.e., lipids, it must be presumed that a "homologous suspension" would also be present in the prior art.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

### **Provisional Obviousness-Type**

Claims 20-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-21 of copending



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Application No. 10/012,702. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the present claims and the co-pending claims are directed to the preparation of the same composition, which includes the steps of centrifuging or filtering. That in the co-pending claims the composition is entitled a "cardioprotective composition" is not distinguishing because such does not impart any physical feature to the composition prepared by the co-pending process over that composition prepared by the present process.


This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Raymond J. Henley III  
Primary Examiner  
Art Unit 1614

June 11, 2005